

## **REMARKS**

The office action dated December 21, 2007, has been studied in detail along with the references cited and applied by the examiner. In response, selected claims have been amended (claims 1, 3, and 7-19) and new claims added (claims 20-31). The pending claims should be read in conjunction with the accompanying arguments and supportive patentability. Further examination and consideration of the application as amended are respectfully requested.

## **THE OFFICE ACTION**

Claims 1-6, 8-13, and 17 were rejected under 35 U.S.C. §103(a) as being unpatentable over Wakeman (US 3317540) in view of Berger (US 4574084).

Claims 1-19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Vandeveld et al. (WO 91/07876) in view of Berger.

Claims 1-19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Harwardt et al. (DE 41 37 544) in view of Berger.

## **REJECTIONS UNDER 35 U.S.C. §103(a)**

### **Berger (U.S. 4,574,084)**

Since the Examiner has combined Berger with several other documents, the Applicant desires to address this reference first and then the conclusions drawn from the combinations of references.

In the last Office Action, the Examiner argues on Page 3 that Berger discloses the "general" teaching that common inflammatory skin diseases can be effectively treated with biocidal compositions that are used for disinfection.

This "generalization" of the teaching of Berger is not correct, if one takes the following example. Sulphuric acid can be used as a biocidal composition for disinfection, since it is known that sulphuric acid will kill any kind of cellular material independent whether it is a human tissue, an animal cell, a bacterium, a fungi or a virus.

However, no one would envisage to treat skin diseases or mucous membranes infected by herpes simplex virae with sulphuric acid. Diseases caused by herpes simplex virae typically appear on lips (herpes labialis) or on the penis (herpes genitalis). If the arguments of the Examiner would be correct, Berger teaches to treat your lips or your penis with sulphuric acid. This is an unlikely form/type of treatment.

Berger merely teaches the preparation of a stabilized, modified, aqueous chlorite solution with a content of peroxide compound. The chlorite solution obtained by this process can be used in multiple ways as discussed hereinafter.

The only generalization one can make with Berger is that aqueous chlorite solutions were already known and the invention now opens the possibility to use these chlorite solutions together with the stabilizing peroxy compounds in a broader manner. On column 7 starting from line 61 it is clearly disclosed that the: "stabilized, modified chlorite solutions according to the invention also have further advantageous uses. Thus, it has been found than in particular dilute chlorite solutions according to the invention have excellent biocidal actions in the broadest sense".

The generalization or broadening is to use this particular combination of a chlorite solution with the peroxide stabilizer in biocidal actions in the broadest sense.

But, this does not teach that any kind of biocidal composition can be used for the treatment of skin diseases (reference is made to the above sulphuric acid example).

On column 8 starting from line 3 the "It" clearly relates to the particular peroxide stabilized, chlorite solution of the invention of Berger and to nothing else.

The chemical compounds now claimed in the present application, i.e. the alkali salts and the alkaline earth salts of tosylchloramides chemically differ from a chlorite solution with a stabilizing peroxide.

Therefore, any teaching given by Berger cannot be transferred to those particular compounds now referred to in independent claims 1 and 20 of the application.

Wakeman (US 3.317,540)

Wakeman discloses the microbiocidal action of quaternary ammonium salts of aromatic sulfonamides. In example IV of Wakeman it is described to make a reaction starting from a commercial grade of chloramine-T with an alkyl dimethyl ethyl-butyl ammonium chloride for obtaining an alkyl dimethyl ethyl-benzyl ammonium salt of the N-chloro-t-toluensulfonamide.

Therefore Wakeman clearly teaches not to use chloramine-T as a biocidal compound, but rather to use chloramine-T as a starting material for preparing the chemical compounds, i.e. the quaternary ammonium salts of N-chloro-t-toluensulfonamide. The same is true with example V.

The subject matter and the entire disclosure of Wakeman concerns the quaternary ammonium compounds but not the alkali or the alkaline earth compounds.

If one reads column 3 starting at line 34 it is clear that the following properties of the described products are dependent "upon the nature of the cationic quaternary ammonium compounds". Variations concern the quaternary ammonium compound only, i.e. how many of the basic N-H bonds are replaced or substituted for which kind of substituent.

With regard to chloramine-T, the teaching of Wakeman is restricted to chloramine-T as a starting compound for preparing the quaternary ammonium

compounds which are the subject matter of Wakeman.

Therefore, the teaching of Wakeman leads away from treatment with alkali or alkaline earth metals such as chloramine-T.

Finally, if one considers the examples given in examples IV and V of Wakeman, all of the treated microbes are bacteria and not a virus in particular not herpes simplex virae. Staphylococcus aureus, salmonella typhosa and aspergillus niger are bacteria. In the listing on columns 3/4 of Wakeman, not one of the applications discloses diseases caused by herpes simplex virae.

There are only indicated to bacteria item (9), (26), (28) and fungi (29). Accordingly, Wakeman completely fails to teach the presently claimed compounds to treat herpes simplex virae.

#### Combination of Wakeman and Berger

It is not apparent how the skilled artisan would combine the teaching of Wakeman with that of Berger, because Wakeman is directed to the reaction products of quaternary ammonium hydroxide with arylsulfonamides and Berger is directed to strongly oxidative compositions of chlorites and oxy-compounds. Further, even if the skilled artisan would make such a combination, he would still not arrive at the teaching of the present invention. Therefore, the combination of Wakeman and Berger cannot render obvious the subject-matter of the present invention.

Moreover, if one combines Wakemen and Berger, one does not come to the teaching of claim 1 and new claim 20, i.e. to treat diseases caused by herpes simplex virae with the alkali and/or alkaline earth salts of tosylchloramide. Starting from Berger, one possibly would replace the chlorite compounds by the chemical compounds of Wakeman, but these are quaternary ammonium salts.

If one starts from Wakeman and looks to Berger, one might possibly add a peroxide compound to the quaternary ammonium aromatic salt of Wakeman for having a better stabilization. But not one of these combinations leads to the

teaching of the amended or new claims.

### Vandevelde

The teaching of Vandevelde is directed to disinfect in, inanimate objects which are contaminated with the HIV-virus. This is the only purpose taught. For example, if a human being who is infected with HIV-virus his/her excrements, sweat, or urine can contain HIV-virus. For disinfecting tables, seats, toilets or the like which were contacted by HIV infected individuals, the active agents of Vandevelde are used.

If such a human being dies, and one prepares him for a funeral one can disinfect his body to avoid contaminations of the people handling the dead body.

The active ingredients of Vandevelde which can contain chloramine-T are described for disinfection matters only. There is absolutely no indication in Vandevelde that chloramine-T is suitable for the treatment of skin diseases, much less herpes simplex virae.

An inanimate body which is contaminated at his surface with HIV-virus due to blood, urine or other excrements does not have a skin disease. This body is already dead and cannot be diseased. A surface, like a toilet, a table or the like does not have a skin disease but is contaminated with HIV-virus containing liquids or excrements.

Vandevelde only teaches to destroy the HIV-virus via the disinfection effect of tosylchloramide-T.

No one would consider Vandevelde's use of these ingredients to teach use as a medicament or pharmaceutical. A dead body, table, or toilet cannot give one any response about pain, allergic reactions or the like with respect to chloramine-T.

Additionally, the HIV-virus is a retrovirus and is totally different from the herpes simplex virus, as already stated in the application when discussing Vandevelde. It is a matter of fact that a HIV-virus is totally different from a herpes simplex virus.

When the HIV-virus appeared in the late seventies of the last century, it was one

of the first attempts of the pharmaceutical professionals to test all compounds known for treating diseases caused by virus to attack the HIV-virus.

But, to date, now more than 30 years later, no chemical compound is on the market which can treat diseases caused by both viruses, i.e. HIV-virus and herpes simplex. Otherwise, billions and billions of dollars would not have been invested in researches for such compounds.

There are chemical compounds known to treat herpes simplex virae, for example the compound Aciclovir, but is not possible to treat HIV-infected people with that compound.

As discussed above, Vandeveldte teaches the disinfection of HIV-contaminated bodies only, but there is no teaching to treat the disease caused by the HIV-virus, i.e. AIDS. There is absolutely no teaching in Vandeveldte to use this compound as a medicament or a pharmaceutical.

Additionally, Vandeveldte does not teach to treat skin diseases, since a dead or inanimate body cannot have a disease to be treated.

#### Combination of Vandeveldte and Berger

As stated above, Berger teaches the use of an aqueous chlorite solution stabilized with a peroxide compound.

If one combines the teaching of Berger with Vandeveldte one may add to the tosylchloramide-T compound of Vandeveldte additionally a peroxide of Berger to stabilize this compound for the purpose of disinfection. If one starts from Vandeveldte, one comes to the same conclusion, i.e. to combine for disinfection purposes the chloramine-T with additional stabilizing peroxide compounds for disinfecting HIV contaminated dead bodies.

However, in each scenario one does not arrive at the method of claim 1.

Vandeveldel is directed to "an agent which acts against retrovirus group viruses, in particular Human Immunodeficiency Virus (HIV), ....." (Please see abstract and Page 1, Lines 3 to 6).

It is to be emphasized that the Human Immunodeficiency Virus does not cause a disease of the skin and in particular does not cause a disease of the skin selected from the skin diseases mentioned in claim 1 of the present invention.

Consequently, Vandeveldel does not motivate the skilled artisan any incentive to consider the method according to the present invention. Further, a combination of Vandeveldel with Berger cannot render obvious the subject-matter of the present invention, since, as outlined above, Berger is concerned with biocide compositions totally distinct from the compounds of the present invention.

Furthermore, as detailed above, none of the structural and functional aspects of Vandeveldel can be used as a basis to reject Applicant's claims. Moreover, Vandeveldel is explicitly restricted to the use of chlorinated organic compounds, which stably and lastingly release chlorine, against retrovirus group viruses, in particular Human Immunodeficiency Virus (HIV) on and/or in inanimate objects, rather than human skin.

#### Harwardt (DE 41 37 544 A1)

Harwardt teaches an antimicrobial combination of different ingredients for antiseptic and disinfection of the skin, of mucous membranes and wounds. On page 2 starting with the headline "Beschreibung", Harwardt discloses that several individual active ingredients have been already known which were suitable for antiseptic or disinfection. These individual ingredients are in particular hydrogen peroxide or chlorine containing compounds like chloramines. On that page starting from line 37 it is stated:

- (German) 'Die Verwendung der bisher gebräuchlichen und beispielhaft genannten Einzelwirkstoffe zu Antiseptik und Desinfektion hat einerseits den Nachteil eines geringeren Wirkungsspektrums und andererseits den Nachteil der aufgrund der in der Regel höheren Einsatzkonzentration größeren Stoffbelastung der Körperoberfläche.'
- (English) "The use of the up to now usual and exemplary stated individual ingredients for antiseptic and disinfection have the disadvantage of a small effective spectrum on the one side and on the other side the disadvantage that the surface of the body is charged with greater amounts of compounds as a rule since one has to use higher concentrations in use."

According to Harwardt the disadvantages can be solved by a particular combination of known individual ingredients which contain compounds which set free chlorine, quaternary ammonium compounds, tensides, Taurodolin or aluminum chloride carbamide and aliphatic carbonic acids.

In Example 1 (Beispiel 1) it is shown the synergistic effect of a combination of hydrogen peroxide with sodium hypochlorite or chloramine-T. The test is done on *pseudomonas aurogenosa* which is a bacterium but not a virus. This is a standard test that does not teach treating skin diseases caused by herpes simplex virae.

Harwardt merely discloses a particular combination of active ingredients for antiseptic and disinfection purposes.

#### Combination of Harwardt and Berger



If one combines Berger and Harwardt (starting from Berger), one skilled in the art would additionally add to the combination of aqueous chlorite solution which are stabilized with peroxide additional compounds known from the "combination" of Harwardt.

If one combines Harwardt and Berger (starting from Harwardt), one skilled in the art would come to the conclusion to possibly add peroxide components to the "combination" of Harwardt for stabilizing this combination.

Harwardt expressly discloses that the single ingredients, for example, chloramine-T alone are not suited for antiseptic or disinfection purposes.

Therefore, the teaching of this combination is to add additional ingredients to support or to enhance the disinfection or antiseptic effect. This teaching is similar to Berger, i.e. to have at least two individual compounds of the aqueous chlorite solution stabilized with a peroxide compound.

The subject matter of the present application is not a disinfection or antiseptic treatment, but a treatment of a skin disease caused by herpes simplex virae. These particular treatments are not addressed in the combination of Harwardt and Berger.

Further, a combination of Harwardt with Berger cannot give the skilled artisan any incentive to consider the subject-matter of the present invention, because Berger itself is also directed to an oxidative disinfection composition (see above).

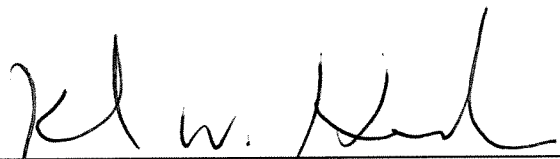
## CONCLUSION


All formal and informal matters having been addressed, this application is in condition for allowance. Early notice to that effect is solicited. Applicant's attorney can be reached at the telephone number below if any further information is needed.

Respectfully submitted,

FAY SHARPE LLP

5/20/08  
Date

  
Karl W. Hauber, Reg. No. 52,999  
1100 Superior Avenue, Seventh Floor  
Cleveland, OH 44114-2579  
216-861-5582

CERTIFICATE OF MAILING OR TRANSMISSION	
I hereby certify that this correspondence (and any item referred to herein as being attached or enclosed) is (are) being	
<input type="checkbox"/> deposited with the United States Postal Service as First Class Mail, addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.	
<input checked="" type="checkbox"/> transmitted to the USPTO by electronic transmission via EFS-Web on the date indicated below.	
Express Mail Label No.:	Signature: 
Date: <u>May 20, 2008</u>	Name: Adeline Machado

N:\HMNZ\200021\AXM0000809V001.docx